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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/003,021	11/14/2001	Joseph Manuel Fernandez	INVIT1140-3	2174
7590	12/30/2004		EXAMINER	
Lisa A. Haile, J.D., Ph.D. GRAY CARY WARE & FREIDENRICH LLP Suite 1100 4365 Executive Drive San Diego, CA 92121-2133			FRONDA, CHRISTIAN L	
			ART UNIT	PAPER NUMBER
			1652	
			DATE MAILED: 12/30/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.	FERNANDEZ ET AL.	
Examiner Christian L Fronda	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 12 October 2004.  
2a) This action is **FINAL**.      2b) This action is non-final.  
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 41-58 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) Claim(s) \_\_\_\_\_ is/are allowed.  
6) Claim(s) 41-58 is/are rejected.  
7) Claim(s) \_\_\_\_\_ is/are objected to.  
8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.  
10) The drawing(s) filed on 14 November 2001 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_  
5) Notice of Informal Patent Application (PTO-152)  
6) Other: \_\_\_\_\_

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## DETAILED ACTION

1. Claims 41-58 are pending and under consideration in this Office Action.

### *Claim Rejections - 35 U.S.C. § 112, 1st Paragraph*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 41-58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' arguments filed 10/12/2004, have been fully considered but they are not persuasive. Applicant's position is that ORFs are well known in the public databases and that applicants do not need to provide an example of every species of a given genus to comply with the written description requirement. The Examiner respectfully disagrees with Applicants' position for the reasons of record as supplemented below.

The claims are in fact genus claims that are directed toward any isolated expression vector comprising any sequence 5'-CACC linked 5' to a start codon of any open reading frame of any nucleic acid from any biological source.

The description in the specification of an isolated expression vector comprising SEQ ID NO: 1 linked 5' to a start codon of yeast open reading frames (ORFs) where the yeast ORFs' expression has been analyzed by Western blot using anti-V5 antibody to detect an epitope tag is not representative of the genus claimed since the genus includes many nucleic acids from many biological sources with widely differing structural, chemical, and physical characteristics. The specification fails to a written description of representative nucleic acid molecules from any bacteria, any fungus, any vertebrate, and any invertebrate as encompassed by the genus claims.

In view of the above considerations, Applicants have failed to sufficiently describe the

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claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 41-58 are rejected under 35 U.S.C. 102(e) as being anticipated by Dubensky, Jr. et al. (US Patent 6,342,372).

Dubensky, Jr. et al. teach an oligonucleotide primer comprising the CACC sequence (SEQ ID No. 69) linked to the 5' start codon ATG of nucleic acids encoding heterologous polypeptides, where the sequences surrounding the ATG start codon from base -9 to +1 that conform to the Kozak consensus sequence for efficient translational initiation (see entire publication, especially column 90, lines 46-58).

Dubensky, Jr. et al. teach eukaryotic expression vectors that contain the above described nucleic acid have in the expressed proteins affinity purification tag for affinity purification of the produced proteins (see column 157, line 67 to column 158, line 5).

The taught expression vectors contain promoters, enhancers, selection marker sequence, and origin of replication (see entire patent, especially Figures 8, 11, and 15; and column 2, line 63 to column 50, line 55).

Thus, the reference teachings anticipate the claimed invention.

***Conclusion***

6. No claim is allowed.

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7. Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF



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TECH 12, 1600